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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/685,802

10/16/2003

Richard Fike

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STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
1100 NEW YORK AVENUE, N.W.
WASHINGTON, DC 20005

EXAMINER

FLOOD, MICHELE C

ART UNIT

PAPER NUMBER

1655

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

03/14/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/685,802	Applicant(s) FIKE ET AL.	
	Examiner Michele Flood	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,11-14,92,93 and 97-108 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,11-14,92,93 and 97-108 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>6/06;7/04;3/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

In the instant case, with regard to the abstract, Applicant should avoid the use of the language, "The present invention relates generally" and "The invention further provides" and "The invention also relates to".

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 92, 93 and 102 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 92 recites the limitation "the reconstituted eukaryotic medium" in line 2.

There is insufficient antecedent basis for this limitation in the claim.

Claim 92 recites the limitation "the desired pH" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claims 93 and 102 recite numerous abbreviations. Abbreviations in the first instance of claims should be expanded upon with the abbreviation indicated in parentheses. The abbreviations can be used thereafter. Abbreviations in the first instance of claims should be expanded upon with the abbreviation indicated in parentheses. The abbreviations can be used thereafter.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2, 11-14, 97-99, 101, 107 and 108 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9,

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11, 12 and 21-23 of U.S. Patent No. 6,383,810 (AK3). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are obvious variants of one another.

Claims 2, 11-14, 92, 93 and 97-108 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9, 11, 12 and 21-23 of U.S. Patent No. 6,383,810 (AK3). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 2, 11-14, 92, 93 and 97-108 are generic to all that is recited in claims 1-9, 11, 12 and 21-23 of U.S. Patent No. 6,383,810. That is, claims 2, 11-14, 92, 93 and 97-108 fall entirely within the scope of claims 1-9, 11, 12 and 21-23 of U.S. Patent No. 6,383,810 (AK3).or in other words, claims 2, 11-14, 92, 93 and 97-108 are anticipated by claims 1-9, 11, 12 and 21-23 of U.S. Patent No. 6,383,810 because the actual process steps, process materials, process conditions, and resulting functional effect and properties of the product made by the instantly claimed process are essentially the same. Specifically, the method of 1-9, 11, 12 and 21-23 of the patent is a method of producing an agglomerated eukaryotic cell culture medium powder, said method comprising agglomerating a dry powder eukaryotic cell culture medium with a solvent by: (a) placing said dry powder eukaryotic cell culture medium into a fluid bed apparatus; (b) introducing said solvent into said dry powder under conditions whereby said powder is moistened; and (c) drying said moistened powder, thereby producing an agglomerated eukaryotic cell culture medium powder, wherein said agglomerated eukaryotic cell culture medium powder exhibits reduced dusting and a larger particle size than does

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said dry powder eukaryotic cell culture medium, which is sterilized after packaging the agglomerated powder by irradiation with gamma rays and which is used for culturing an animal cell, a mammalian cell, a human cell, an insect cell, a nematode cell, a fungal cell, a plant cell and a yeast cell. The patent method provides for the production of agglomerated eukaryotic media comprising the use of a solvent to agglomerate a eukaryotic dry powder medium (for example, incorporating a solvent into the solvent such as a phospholipid, a sphingolipid, a fatty acid or cholesterol). The patent method clearly defines the term agglomerated eukaryotic cell medium as a medium for culturing insect cells (most preferably *Drosophila* cells, *Spodoptera* cells and *Trichoplusia* cells), nematode cells (most preferably *C. elegans* cells) and mammalian cells (most preferably CHO cells, COS cells, VERO cells, BHK cells, AE-1 cells, SP2/0 cells, L5.1 cells, hybridoma cells or human cells), as well as a fungal cell, a plant cell and a yeast cell. The patent clearly defines a method of producing an agglomerated eukaryotic cell medium wherein the agglomerated eukaryotic medium powder comprises supplements such as cytokines (including growth factors (such as EGF, aFGF, bFGF, HGF, IGF-1, IGF-2, NGF and the like); and, lipids (such as phospholipids, cholesterol, bovine cholesterol concentrate, fatty acids, sphingolipids and the like). The specification of the instant application, like the patent, clearly discloses a method of making an agglomerated eukaryotic medium wherein upon reconstitution with water, the reconstituted eukaryotic medium has a pH that is desirable for culturing a eukaryotic cell

Thus, Claims 2, 11-14, 92, 93 and 97-108 are deemed obvious variants of the limitations of the patented subject matter as per the supporting portions of U.S. Patent No. 6,083,510 and the instant application.

Claim 2 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 11/434,513. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are obvious variants of one another.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 2, 92, 97-99 and 101-106 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 5-11 of copending Application No. 11/669,827. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are obvious variants of one another.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


MICHELE FLOOD
PRIMARY EXAMINER

Michele Flood
Primary Examiner
Art Unit 1655

MCF
February 19, 2007